



United States
General Accounting Office
Washington, D.C. 20548

Resources, Community, and
Economic Development Division

B-249639



147492

September 2, 1992

The Honorable Charles Stenholm
Chairman
The Honorable Steve Gunderson
Ranking Minority Member
Livestock, Dairy and Poultry Subcommittee
Committee on Agriculture
House of Representatives

This letter responds to your request for information on (1) any differences in the Food and Drug Administration's (FDA) inspection and sampling procedures for imported dairy products¹ and other imported foods, (2) FDA's inspection requirements for imported fresh/ frozen milk and cream under the Federal Import Milk Act, and (3) the differences in FDA's inspection and sampling procedures for domestic and imported dairy products. We are also providing information on the quantity of imported dairy products that FDA has inspected, analyzed, detained, and found to be in violation of U.S. standards since 1985, by country of origin (see enclosure).

In summary, FDA's inspection procedures for imported dairy products are similar to those the agency uses for all other food imports. To regulate the safety of all imported foods, including dairy products, FDA relies primarily on sampling and testing of products when they are offered for entry at a U.S. port. FDA generally targets for inspection those products that have a history of violations. Although FDA sampled, on average, about 4.3 percent of imported dairy products during fiscal years 1986 through 1990, the sampling rate varied from product to product. During this period, FDA sampled about 4.5 percent of imported cheese entries but only 1.2 percent of imported butter entries. FDA collected and analyzed 5,217 physical samples of imported dairy products

¹As agreed with your office, this review focused on imported cheese, casein, butter, and dried milk/frozen cream. These account for about 82 percent of all dairy products imported into the United States.

GAO/RCED-92-258R, FDA's Inspection of Imported Dairy Products

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between fiscal years 1985 and 1991 for microbial contamination, pesticide residues, and filth. About 477 samples, or 9 percent, were found to be in violation of U.S. food safety standards for these contaminants.

The Federal Import Milk Act requires FDA to ensure through inspections or certifications of a foreign government that fresh/frozen milk and cream is properly produced and handled before it is imported into the United States. Currently, only one country--New Zealand--exports frozen cream to the United States under the provisions of the act. FDA has not conducted any foreign inspections of its own and has relied on the certification of the foreign government to ensure that imported milk and cream meet the requirements of the act.

Unlike its inspection program for imported dairy products, FDA does not rely solely on sampling and testing finished products to ensure the safety of domestic dairy products. Ensuring the safety of domestic dairy products is a multiagency responsibility carried out by FDA, state agencies, and the U.S. Department of Agriculture (USDA). The safety of domestic dairy products is ensured through inspections of raw materials and processing facilities, the use of good manufacturing practices, and limited sampling and testing of finished products.

BACKGROUND

Since 1986 the United States has imported over \$22 billion worth of food annually. Imported dairy products make up about \$844 million, or 4 percent, of this total. Cheese and casein² constitute about 80 percent of the value of all dairy products imported into the United States, while butter and dry milk/frozen cream account for about 2 percent.

Under the Federal Food, Drug, and Cosmetic Act, as amended, FDA is responsible for ensuring that imported FDA-regulated foods, including dairy products, meet the same safety and labeling standards as domestic products. These standards require that all FDA-regulated food products be safe, pure, wholesome, and accurately labeled. FDA's Center for Food Safety and Applied Nutrition is responsible for providing guidance to FDA's district offices and monitoring imported food products. Import inspections are carried out by 20 FDA district offices across the country.

²Casein is the phosphoprotein in milk and is used for both food and nonfood purposes.

FDA'S INSPECTION PROCEDURES FOR
IMPORTED DAIRY PRODUCTS

FDA's inspection program for all imported foods, including dairy products, is a complex process that depends, to a great extent, on the knowledge and judgment of FDA inspectors and on the decisions of the importer in response to FDA's actions. When an import entry arrives at a U.S. port, the Customs Service notifies FDA of FDA-regulated products. FDA-regulated imported food entries receive an initial records review by an FDA inspector. On the basis of this review, an FDA inspector determines whether further examination is needed or whether the product may be released into the U.S. market. If FDA decides not to inspect a shipment, a May Proceed Notice is sent to the Customs Service and the importer.

Imported foods may receive one of three kinds of additional FDA inspection. The first is a documentary review--a detailed review of all the paperwork that accompanies the entry. The second is a wharf examination--a visual inspection to determine if there are any noticeable defects, such as labeling, insect infestation, or filth. The third is a physical examination--an FDA inspector collects a sample of the product for a laboratory analysis. The decision to sample a shipment is based on (1) the nature of the product; (2) FDA priorities as outlined in import alerts, compliance programs, and short-term surveys; and (3) historical evidence of recurring problems with the product or importer. If FDA decides to sample a shipment, it sends a Notice of Sampling to the Customs Service and the importer, which is required to hold the shipment intact pending further notice. Samples of imported dairy shipments are sent to an FDA laboratory for microbial, pesticide, and filth analysis. The results of the laboratory analysis will help determine whether a shipment should be released or detained.

If the results of any FDA examination, including documentary reviews and wharf examinations, indicate that the product violates U.S. food safety or labeling standards, FDA will so inform the Customs Service and the importer and set a hearing date through a Notice of Detention and Hearing. At the hearing the importer can demonstrate why the imported product meets all U.S. requirements or how the shipment can be made

eligible for entry.³ For items refused admission to the United States, the importer is required to export or destroy the shipment under the Customs Service's supervision and direction.

According to FDA officials, there is no significant difference in the inspection procedures for all imported foods and imported dairy products. As it does for other imported foods, FDA uses import alerts to its districts to identify imported dairy products that have a history of violating U.S. food safety standards and should be inspected. Those importers/exporters or products that consistently violate U.S. standards may also be placed on automatic detention. Automatic detention allows FDA inspectors to detain a product without sampling and analysis and shifts to the importer the burden of proving that the product meets U.S. standards. Imported dairy products are generally placed on automatic detention for microbial contamination, such as listeria and salmonella, according to FDA officials.

LIMITED FDA SAMPLING OF IMPORTED DAIRY ENTRIES

For fiscal years 1986 through 1990, we found that FDA sampled, on average, about 4.3 percent of all shipments of cheese, casein, butter, and dry milk/frozen cream that were imported into the United States. However, FDA sampled imported cheese entries at a higher rate than it did the other three products. FDA sampled, on average, about 4.5 percent of imported cheese entries, 2.5 percent of imported casein entries, 1.2 percent of imported butter entries, and 2.4 percent of imported dry milk/frozen cream entries.

Of the total 5,217 samples of imported dairy products that FDA collected and analyzed between fiscal years 1985 through 1991 for microbial contamination, pesticide residues, and filth, 477 samples, or about 9 percent, violated U.S. food safety standards for these contaminants. The average violation rate for imported cheese over this 7-year period was about 10 percent; for imported casein, 2 percent; and for

³This is done through reconditioning, which involves manipulating the product to bring it into compliance with U.S. standards, such as relabeling.

imported butter, 65 percent. No samples of imported dry milk were found to be in violation.⁴

In the past we have reported our concerns about FDA's low sampling rate for all imported products--about 2 percent--and the limited coverage that this low level of sampling provides for imported products.⁵ FDA officials are concerned about the reduction in the agency's level of inspection for imported foods. In a 1990 report on the efficiency of FDA's import inspection practices, FDA reported that while the volume of imported entries has tripled since the 1970s, FDA resources have not had a corresponding increase.⁶ As a result, the proportion of entries inspected by FDA has declined by over 50 percent. FDA officials told us that they would like to increase the level of inspection for all imported foods but would need additional resources to do so.

INSPECTION REQUIREMENTS OF
THE FEDERAL IMPORT MILK ACT

Under the Federal Import Milk Act (21 U.S.C. 141-149), milk and cream may be imported into the United States only under a permit issued by the Secretary of Health and Human Services. The purpose of the act is to ensure that foreign milk producers compete with domestic producers in U.S. markets under common standards and to protect public health by regulating the importation of milk and cream into the United States.

The Federal Import Milk Act generally requires the Secretary of Health and Human Services to ensure that (1) foreign dairy herds are healthy, including being free from tuberculosis; (2) dairy farms and plants meet certain minimum sanitary

⁴Because FDA's sampling decisions are targeted on those products or importers that have a history of violations and are not drawn randomly, these numbers may not represent an accurate estimate of the violation rates for these products.

⁵Food Safety and Quality: FDA Can Improve Monitoring of Imported Cheese (GAO/RCED-92-210, July 6, 1992); Imported Foods: Opportunities to Improve FDA's Inspection Program (GAO/HRD-89-88, Apr. 28, 1989); and Pesticides: Better Sampling and Enforcement Needed on Imported Food (GAO/RCED-86-219, Sept. 26, 1986).

⁶The Efficiency of FDA Import Practices, FDA (Washington, D.C.: Mar. 1990).

standards; (3) raw and pasteurized milk and cream have bacteria counts that do not exceed certain limits; and (4) the temperature of imported milk or cream at the time of transportation does not exceed 50 degrees Fahrenheit. Some of these requirements may be waived when imported milk is produced near a U.S. processing plant and/or will be subjected to a sterilization process. If all of the applicable requirements are met, an export permit for milk/cream is issued. The act provides the Secretary with certain discretion in conducting the inspections. In addition to inspections "made by or under [his] direction," the Secretary may accept a certification from a foreign government and/or any state or municipality of the United States.

Currently, New Zealand is the only country exporting products to the United States under the act, according to an FDA official.⁷ The New Zealand Dairy Board is permitted to export frozen cream to the United States under the act. The required certifications of dairy cows, farms, and plants are performed annually by New Zealand's Ministry of Agriculture and Fisheries. Every year the New Zealand Dairy Board must renew its permit and submit the New Zealand Ministry of Agriculture and Fisheries' inspection reports for dairy farm and milk plant sanitation and dairy farm animal health to FDA for review.

According to FDA officials, FDA cannot conduct the inspections required under the act because it does not have jurisdiction over foreign dairy farms and processing facilities. FDA can inspect foreign facilities only when invited to do so by a foreign government. According to an FDA branch director, the agency has never conducted any inspections under the act and has relied on the inspection certification of the foreign government.

DOMESTIC DAIRY SAFETY IS ENSURED
BY MULTIAGENCY INSPECTIONS

The domestic dairy inspection process, unlike FDA's import inspection process, does not rely solely on end-product inspections to ensure safety. According to FDA officials, domestic dairy products receive two levels of inspection. The first level ensures the safety of the domestic milk

⁷In the past Canada and Germany have also exported milk/cream under the act to the United States, according to an FDA official.

supply through dairy farm inspections; the second level ensures the compliance of dairy processing plants with good manufacturing practices. Although FDA is the principal agency responsible for ensuring the safety of domestic dairy products, it has delegated some of this responsibility to state agencies through a memorandum of understanding. State agencies are responsible for inspecting the majority of dairy farm and processing plants, with FDA oversight. FDA prefers to target its limited inspection resources on dairy processors with a history of violations or high-risk processors, such as those that use unpasteurized milk for their products, according to FDA officials. FDA generally inspects dairy processing plants every 4 to 5 years, while state inspections are generally conducted yearly; some states conduct them quarterly.

End-product sampling by FDA is not the only mechanism for ensuring the safety of domestic dairy products, as it is for imported dairy products. FDA inspectors may collect samples of domestic dairy products as evidence to support observed or suspected problems, such as unsanitary facilities and possible bacteriological contamination, during their inspections of the dairy processing plants. Samples of domestic dairy products may also be collected and analyzed by FDA for general surveillance purposes as well as for determining compliance of the product with federal economic standards, such as milk fat and other ingredient contents.

In addition, domestic dairy facilities that request and pay for USDA's grading services are inspected by a USDA inspector. According to USDA, this inspection program is widely used. In October 1991 over 500 dairy facilities nationwide had been inspected and approved for USDA's grading service. Although the primary objective of this service is to determine the quality and grade of dairy products, dairy product quality is highly dependent on the use of sanitary manufacturing practices, according to a USDA official. Therefore, dairy facilities that request grading services are inspected at least twice a year for compliance with USDA requirements for dairy plants. USDA's requirements include specifications for the physical condition of plant facilities, raw materials, and equipment and for methods of operation. However, USDA does not have the authority to enforce good manufacturing practices or food safety standards. Therefore, for dairy processing facilities that violate food safety standards, USDA can, at the most, withdraw its grading service in an attempt to get the establishment to comply with food safety regulations. By agreement, USDA's Agricultural Marketing Service is required

to notify FDA of any unsanitary conditions at domestic dairy processing plants for regulatory action. We recently reported on problems with the domestic inspection system for dairy products,⁸ including the fact that USDA does not always promptly notify FDA when USDA inspectors find unsanitary conditions at dairy plants.

While inspection and violation rates of imported and domestic dairy products are not comparable because of differences in the inspection systems, as explained above, microbiological contamination in domestic dairy products has ranged from about 7 percent to about 10 percent. During fiscal years 1986 and 1987, FDA inspected 1,016 domestic dairy processing plants (not including cheese manufacturing plants) as part of a safety initiative on domestic dairy products. FDA found that 70, or about 7 percent, of these dairy plants had violations for microbiological contamination in their finished products. During fiscal years 1985 and 1986, FDA sampled and analyzed 811 samples of domestic cheese (both hard and soft varieties) and found a microbiological contamination rate of about 10 percent.

AGENCY VIEWS

We discussed the information in this letter with officials of FDA's Center for Food Safety and Applied Nutrition, Office of Regulatory Affairs, and Office of the Commissioner, who generally agreed with the facts as presented. Where appropriate, changes have been made on the basis of these discussions to further clarify the information presented.

SCOPE AND METHODOLOGY

We interviewed officials and obtained documentation from the Office of Regulatory Affairs and the Center for Food Safety and Applied Nutrition at FDA's headquarters in Washington, D.C., and Rockville, Maryland, and at FDA's Los Angeles and New York district offices, which serve the two largest U.S. ports of entry for food imports. For information on the quantities of the four dairy products inspected, detained, and found in violation for fiscal years 1985 through 1990, we relied extensively on data provided to us by FDA from its national data bases--the Program Oriented Data System and Import Detention System, which are the only official data

⁸Food Safety and Quality: Uniform, Risk-based Inspection System Needed to Ensure Safe Food Supply (GAO/RCED-92-152, June 26, 1992).

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available. Because of time constraints, we performed only a limited reliability assessment of the data and found multiple errors in the data fields for quantity of product sampled and detained. We have corrected the errors that we identified to the extent possible, but we cannot fully ensure the accuracy of the agency data that we have used in the enclosure.

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As agreed with your office, the submission of this information completes our response to 7 of the 14 issues raised in your October 17, 1991, request, and the remaining issues will be addressed in a follow-on review.

If you have any questions concerning this information, please contact me at (202) 275-5138.



John W. Harman
Director, Food and
Agriculture Issues

Enclosure

INSPECTION, DETENTION, AND
VIOLATION RATES FOR U.S. DAIRY IMPORTS

This enclosure provides information on FDA's inspection, detention, and violation rates for U.S. dairy imports of cheese, casein, butter, and dry milk/frozen cream. The information is organized by country of origin for fiscal years 1985 to 1991. The tables fall into three major sections:

- Tables 1 to 4 show the six countries from which the United States imported the largest quantities of cheese, butter, casein, and dry milk/frozen cream for fiscal years 1985 through 1990. We developed these data using information obtained from the U.S. Department of Agriculture's (USDA) Foreign Agricultural Trade of the United States.
- Tables 5 to 8 show the number of (1) documentary reviews (including label reviews), (2) wharf examinations, (3) physical samples analyzed, and (4) physical samples analyzed and found to be in violation of U.S. standards for microbial contamination, pesticide residue, and filth for the six countries from which the United States imported the greatest quantities of cheese, casein, butter, and dry milk/frozen cream between fiscal years 1985 and 1991. We developed this information from the data provided to us by Food and Drug Administration officials from the agency's Program Oriented Data System.
- Tables 9 to 12 show the quantity and number of imported cheese, casein, butter, and dry milk/frozen cream entries for which FDA issued a Notice of Detention and Hearing on the basis of potential health hazards or for nonhealth-related reasons from the six countries from which the United States imported the greatest quantities of each product, for fiscal years 1985 to 1991. According to FDA officials, nonhealth-related detentions include detentions for any of the following reasons: mandatory labeling omitted, labeling not in English, substandard identity, inconspicuous labeling, violation of the Fair Packaging and Labeling Act, short weight, false/misleading labeling, and omission of nutritional labeling. Most other detentions are for health-related concerns. Information included in tables 9 to 12 is based on reports we developed from data provided to us by FDA officials from the agency's Import Detention System.

Table 1: Largest Exporters of Cheese to the United States for Fiscal Years 1985-90

Country of origin	Fiscal year						6-year average	Average percent
	1985	1986	1987	1988	1989	1990		
Denmark								
Quantity	17,660	15,593	11,387	9,355	9,988	13,353	12,889	9.99
Value	\$48,463	\$48,910	\$41,920	\$35,800	\$34,318	\$42,208	\$41,937	10.81
Finland								
Quantity	11,491	9,936	10,198	8,681	8,690	8,310	9,551	7.40
Value	\$31,686	\$28,222	\$27,372	\$24,807	\$25,741	\$25,969	\$27,300	7.04
France								
Quantity	12,316	10,899	10,079	8,584	8,310	9,017	9,868	7.85
Value	\$38,557	\$43,029	\$47,895	\$44,909	\$40,440	\$46,294	\$43,521	11.22
Italy								
Quantity	14,962	11,854	14,588	14,334	17,830	20,127	15,616	12.10
Value	\$45,273	\$44,543	\$60,128	\$61,652	\$64,078	\$77,061	\$58,789	15.16
Netherlands								
Quantity	7,512	6,681	7,428	6,657	7,671	15,022	8,329	6.45
Value	\$18,499	\$18,603	\$23,722	\$21,113	\$22,392	\$37,909	\$23,706	6.11
New Zealand								
Quantity	18,974	23,148	12,648	19,467	18,087	13,818	17,657	13.68
Value	\$36,241	\$44,745	\$24,680	\$36,374	\$37,214	\$30,576	\$34,972	9.02
Others								
Quantity	51,799	56,149	59,645	52,480	48,119	62,510	55,117	42.72
Value	\$145,378	\$157,605	\$171,058	\$150,781	\$140,454	\$179,966	\$157,540	40.63
Total								
Quantity	134,714	134,260	128,973	118,558	118,695	141,957	129,026	
Value	\$364,097	\$385,657	\$396,775	\$375,436	\$364,637	\$439,983	\$387,764	

Note: Quantity is measured in metric tons.
Value is represented in thousands of dollars.

Source: USDA, Foreign Agricultural Trade of the United States.

Table 2: Largest Exporters of Casein to the United States for Fiscal Years 1985-90

Country of origin	Fiscal year						6-year average	Average percent
	1985	1986	1987	1988	1989	1990		
Australia								
Quantity	6,204	5,608	6,243	6,473	3,909	2,872	5,218	5.35
Value	\$10,892	\$9,834	\$11,437	\$17,923	\$18,737	\$11,862	\$13,448	4.71
Denmark								
Quantity	3,008	5,503	7,606	5,894	4,503	5,072	5,264	5.40
Value	\$6,753	\$11,625	\$15,924	\$23,031	\$23,443	\$22,969	\$17,291	6.05
France								
Quantity	5,544	2,617	3,302	3,945	4,136	8,386	4,655	4.77
Value	\$10,196	\$5,108	\$7,275	\$12,641	\$18,551	\$36,001	\$14,962	5.24
Ireland								
Quantity	26,508	29,577	33,278	33,473	25,932	31,717	30,081	30.84
Value	\$57,286	\$61,731	\$71,613	\$99,076	\$120,068	\$154,287	\$94,010	32.90
Netherlands								
Quantity	3,370	3,375	6,425	6,301	5,533	7,584	5,448	5.59
Value	\$7,754	\$7,979	\$17,065	\$21,176	\$26,612	\$38,999	\$19,931	6.98
New Zealand								
Quantity	52,399	44,279	41,564	30,230	20,409	29,404	36,391	37.31
Value	\$101,475	\$84,187	\$83,632	\$91,791	\$96,877	\$133,073	\$98,506	34.48
Others								
Quantity	11,077	10,064	11,722	10,397	10,334	9,310	10,484	10.75
Value	\$18,421	\$16,858	\$23,268	\$30,375	\$46,860	\$29,689	\$27,579	9.65
Total								
Quantity	108,110	101,023	110,140	96,713	74,856	94,405	97,541	
Value	\$212,777	\$197,322	\$230,214	\$296,013	\$351,148	\$426,880	\$285,726	

Note: Quantity is measured in metric tons.
Value is represented in thousands of dollars.

Source: USDA, Foreign Agricultural Trade of the United States.

Table 3: Largest Exporters of Butter to the United States for Fiscal Years 1985-90

Country of origin	Fiscal year						6-year average	Average percent
	1985	1986	1987	1988	1989	1990		
Canada								
Quantity	78	112	145	2	23	144	84	6.28
Value	\$120	\$129	\$208	\$5	\$24	\$246	\$122	4.82
Denmark								
Quantity	175	182	165	160	137	140	160	11.95
Value	\$383	\$376	\$338	\$323	\$344	\$422	\$364	14.38
France								
Quantity	27	52	32	28	344	443	154	11.52
Value	\$91	\$209	\$145	\$121	\$643	\$872	\$347	13.69
Ireland								
Quantity	162	170	96	116	411	429	231	17.25
Value	\$283	\$249	\$147	\$164	\$546	\$489	\$313	12.36
New Zealand								
Quantity	243	195	333	348	563	381	344	25.71
Value	\$643	\$503	\$680	\$605	\$1,086	\$870	\$731	28.87
Germany								
Quantity	55	76	53	134	91	85	82	6.16
Value	\$170	\$151	\$126	\$276	\$172	\$233	\$188	7.42
Others								
Quantity	120	132	86	177	469	711	283	21.13
Value	\$266	\$283	\$221	\$347	\$755	\$933	\$468	18.46
Total								
Quantity	860	919	910	963	2,038	2,333	1,337	
Value	\$1,956	\$1,900	\$1,865	\$1,841	\$3,570	\$4,065	\$2,533	

Note: Quantity is measured in metric tons.
Value is represented in thousands of dollars.

Source: USDA, Foreign Agricultural Trade of the United States.

Table 4: Largest Exporters of Dry Milk/Frozen Cream to the United States for Fiscal Years 1985-90

Country of origin	Fiscal year						6-year average	Average percent
	1985	1986	1987	1988	1989	1990		
Australia								
Quantity	706	602	677	556	76	571	531	3.44
Value	\$510	\$479	\$494	\$640	\$131	\$1,053	\$551	3.59
Canada								
Quantity	4,979	5,765	6,351	7,288	8,025	7,385	6,632	42.92
Value	\$3,836	\$4,189	\$4,419	\$4,894	\$6,833	\$6,206	\$5,063	32.99
Netherlands								
Quantity	2,219	1,655	1,346	766	1,124	2,076	1,531	9.91
Value	\$1,596	\$1,234	\$925	\$626	\$1,028	\$1,653	\$1,177	7.67
New Zealand								
Quantity	7,011	7,047	5,512	5,572	4,989	5,389	5,920	38.31
Value	\$8,108	\$9,645	\$7,458	\$7,733	\$7,128	\$7,738	\$7,968	51.93
United Kingdom								
Quantity	0	174	441	476	287	609	331	2.14
Value	\$0	\$146	\$357	\$418	\$294	\$530	\$291	1.90
Germany								
Quantity	894	215	0	63	0	95	211	1.37
Value	\$565	\$147	\$0	\$69	\$0	\$54	\$139	0.91
Others								
Quantity	601	307	81	154	391	245	297	1.92
Value	\$301	\$98	\$66	\$150	\$228	\$94	\$156	1.02
Total								
Quantity	16,410	15,765	14,408	14,875	14,892	16,370	15,453	
Value	\$14,916	\$15,938	\$13,719	\$14,530	\$15,642	\$17,328	\$15,346	

Note: Quantity is measured in metric tons.
Value is represented in thousands of dollars.

Source: USDA, Foreign Agricultural Trade of the United States.

Table 5: Documentary Reviews, Wharf Examinations, Physical Analyses, and Physical Samples Found Violative for Imported Cheese by Country of Origin, Fiscal Years 1985-91

Country of origin	Type of FDA examination	Fiscal year							Total
		1985	1986	1987	1988	1989	1990	1991	
Denmark	Documentary	0	0	0	4	1	0	21	26
	Wharf	13	1	2	2	2	1	8	29
	Physical	25	36	39	86	63	106	106	461
	Violations ^a	0	1	1	1	0	5	10	18
Finland	Documentary	0	0	0	1	0	0	0	1
	Wharf	0	0	0	0	0	2	0	2
	Physical	0	8	14	4	10	21	3	60
	Violations ^a	0	1	0	0	0	2	0	3
France	Documentary	16	804	153	26	37	254	46	1,336
	Wharf	59	140	41	8	23	30	39	340
	Physical	137	1,256	161	112	82	172	321	2,241
	Violations ^a	59	63	11	7	7	35	32	214
Italy	Documentary	5	4	156	53	66	108	22	414
	Wharf	9	9	4	2	6	5	8	43
	Physical	25	137	102	87	47	84	65	547
	Violations ^a	3	16	6	4	3	18	14	64
Netherlands	Documentary	1	0	1	13	8	8	1	32
	Wharf	0	3	12	3	4	3	4	29
	Physical	6	23	16	39	22	52	46	204
	Violations ^a	0	0	1	1	1	2	3	8
New Zealand	Documentary	0	0	0	0	0	0	0	0
	Wharf	0	0	0	5	0	1	0	6
	Physical	0	1	4	1	2	3	3	14
	Violations ^a	0	1	0	0	0	0	0	1
Others	Documentary	5	97	77	21	22	38	13	273
	Wharf	33	77	101	37	22	29	21	320
	Physical	54	170	235	174	175	305	220	1,333
	Violations ^a	14	21	21	12	13	50	22	153
Total	Documentary	27	905	387	118	134	408	103	2,082
	Wharf	114	230	160	57	57	71	80	769
	Physical	247	1,631	571	503	401	743	764	4,860
	Violations ^a	76	103	40	25	24	112	81	461

^aNumber of physical samples analyzed by FDA and found violative.

Source: GAO analysis of FDA data.

Table 6: Documentary Reviews, Wharf Examinations, Physical Analyses, and Physical Samples Found Violative for Imported Casein by Country of Origin, Fiscal Years 1985-91

Country of origin	Type of FDA Examination	Fiscal year							Total
		1985	1986	1987	1988	1989	1990	1991	
Australia	Documentary	0	0	0	0	0	0	0	0
	Wharf	0	0	0	0	0	0	0	0
	Physical	2	4	2	1	1	0	0	10
	Violations ^a	0	0	0	0	0	0	0	0
Denmark	Documentary	0	0	0	0	0	0	0	0
	Wharf	0	0	0	0	0	0	0	0
	Physical	5	1	1	0	0	2	2	11
	Violations ^a	0	0	0	0	0	0	0	0
France	Documentary	0	0	0	0	1	0	0	1
	Wharf	0	0	0	0	0	0	0	0
	Physical	62	7	0	3	1	1	0	74
	Violations ^a	0	0	0	0	0	0	0	0
Ireland	Documentary	0	0	0	0	0	0	0	0
	Wharf	0	0	0	1	0	0	1	2
	Physical	1	5	7	6	5	7	1	32
	Violations ^a	0	0	0	0	2	1	0	3
Netherlands	Documentary	0	0	0	0	0	0	0	0
	Wharf	0	0	0	0	1	0	0	1
	Physical	4	0	0	5	2	1	3	15
	Violations ^a	0	0	0	0	0	0	0	0
New Zealand	Documentary	0	0	0	0	0	0	0	0
	Wharf	0	0	1	0	0	0	0	1
	Physical	37	22	9	5	2	3	1	79
	Violations ^a	0	0	0	0	0	1	0	1
Others	Documentary	0	0	0	0	0	0	1	1
	Wharf	0	7	0	0	0	0	1	8
	Physical	29	44	28	1	4	1	2	109
	Violations ^a	0	0	1	0	0	0	0	1
Total	Documentary	0	0	0	0	1	0	1	2
	Wharf	0	7	1	1	1	0	2	12
	Physical	140	83	47	21	15	15	9	330
	Violations ^a	0	0	1	0	2	2	0	5

^aNumber of physical samples analyzed by FDA and found violative.

Source: GAO analysis of FDA data.

Table 7: Documentary Reviews, Wharf Examinations, Physical Analyses, and Physical Samples Found Violative for Imported Butter by Country of Origin, Fiscal Years 1985-91

Country of origin	Type of FDA examination	Fiscal year							Total
		1985	1986	1987	1988	1989	1990	1991	
Canada	Documentary	0	0	0	0	0	0	0	0
	Wharf	0	1	0	0	0	0	0	1
	Physical	0	0	0	0	0	0	1	1
	Violations ^a	0	0	0	0	0	0	0	0
Denmark	Documentary	0	0	0	0	0	0	0	0
	Wharf	0	0	0	0	0	0	0	0
	Physical	0	1	0	0	0	0	0	1
	Violations ^a	0	0	0	0	0	0	0	0
France	Documentary	0	0	0	0	0	0	0	0
	Wharf	0	0	0	0	0	0	0	0
	Physical	1	0	1	0	0	1	0	3
	Violations ^a	0	0	0	0	0	1	0	1
Ireland	Documentary	0	0	0	0	0	0	0	0
	Wharf	1	1	0	0	0	0	0	2
	Physical	0	0	0	0	1	0	1	2
	Violations ^a	0	0	0	0	0	0	0	0
New Zealand	Documentary	0	0	0	0	0	0	0	0
	Wharf	1	1	0	0	0	0	0	2
	Physical	0	0	0	0	0	0	0	0
	Violations ^a	0	0	0	0	0	0	0	0
Germany	Documentary	0	0	0	0	0	0	0	0
	Wharf	0	0	0	0	0	0	0	0
	Physical	0	0	0	0	0	0	0	0
	Violations ^a	0	0	0	0	0	0	0	0
Others	Documentary	0	0	0	0	0	7	0	7
	Wharf	0	0	1	0	0	0	0	1
	Physical	0	0	0	1	0	9	0	10
	Violations ^a	0	0	0	1	0	9	0	10
Total	Documentary	0	0	0	0	0	7	0	7
	Wharf	2	3	1	0	0	0	0	6
	Physical	1	1	1	1	1	10	2	17
	Violations ^a	0	0	0	1	0	10	0	11

^aNumber of physical samples analyzed by FDA and found violative.

Source: GAO analysis of FDA data.

Table 8: Documentary Reviews, Wharf Examinations, and Physical Analyses for Imported Dry Milk/Frozen Cream by Country of Origin, Fiscal Years 1985-91

Country of origin	Type of FDA examination	Fiscal year							Total
		1985	1986	1987	1988	1989	1990	1991	
Australia	Documentary	0	0	0	0	0	0	0	0
	Wharf	0	0	0	0	0	0	0	0
	Physical	0	0	0	0	0	0	0	0
Canada	Documentary	0	0	0	0	0	0	0	0
	Wharf	1	2	3	0	0	0	0	6
	Physical	3	2	1	0	1	0	0	7
Netherlands	Documentary	0	0	0	0	0	0	0	0
	Wharf	0	0	0	0	0	0	0	0
	Physical	0	0	0	0	0	0	0	0
New Zealand	Documentary	0	0	0	0	0	0	0	0
	Wharf	0	0	0	0	0	0	0	0
	Physical	0	0	0	1	0	0	0	1
United Kingdom	Documentary	0	0	0	0	0	0	0	0
	Wharf	0	0	0	0	0	0	0	0
	Physical	0	0	0	0	0	0	0	0
Germany	Documentary	0	0	0	0	0	0	0	0
	Wharf	0	0	0	0	0	0	0	0
	Physical	0	0	0	0	0	0	0	0
Others	Documentary	0	0	0	0	0	0	0	0
	Wharf	1	1	1	0	0	0	0	3
	Physical	0	0	0	0	0	2	0	2
Total	Documentary	0	0	0	0	0	0	0	0
	Wharf	2	3	4	0	0	0	0	9
	Physical	3	2	1	1	1	2	0	10

Note: No physical samples of imported dry milk/frozen cream were found in violation of U.S. safety standards.

Source: GAO analysis of FDA data.

Table 9: Detentions of Imported Cheese for Health-related Reasons by Country of Origin, Fiscal Years 1985-91

Country of origin	Fiscal year							Total
	1985	1986	1987	1988	1989	1990	1991	
Denmark								
Entries detained	0	0	0	7	0	0	4	11
Quantity (lbs.)	0	0	0	16,156	0	0	10,565	26,721
Finland								
Entries detained	0	1	1	0	0	0	0	2
Quantity (lbs.)	0	20,592	36,704	0	0	0	0	57,296
France								
Entries detained	48	216	225	18	10	12	9	538
Quantity (lbs.)	53,317	256,249	844,345	11,058	2,023	8,267	2,082	1,177,341
Italy								
Entries detained	6	9	184	7	1	6	5	218
Quantity (lbs.)	364	2,427	362,021	37,585	42,988	96,265	2,486	544,136
Netherlands								
Entries detained	0	0	0	1	1	0	0	2
Quantity (lbs.)	0	0	0	5,885	43,780	0	0	49,665
New Zealand								
Entries detained	0	0	0	0	0	0	0	0
Quantity (lbs.)	0	0	0	0	0	0	0	0
Others								
Entries detained	9	24	23	12	13	15	14	110
Quantity (lbs.)	59,792	132,529	146,801	162,145	402,014	196,965	228,000	1,328,246
Total								
Entries detained	63	250	433	45	25	33	32	881
Quantity (lbs.)	113,473	411,797	1,389,871	232,829	490,805	301,497	243,133	3,183,405

Source: GAO analysis of FDA data.

Table 10: Detentions of Imported Cheese for Nonhealth-related Reasons by Country of Origin, Fiscal Years 1985-91

Country of origin	Fiscal year							Total
	1985	1986	1987	1988	1989	1990	1991	
Denmark								
Entries detained	2	1	0	6	8	10	7	34
Quantity (lbs.)	798	40,907	0	50,258	81,686	104,620	151,006	429,275
Finland								
Entries detained	0	0	0	0	2	2	1	5
Quantity (lbs.)	0	0	0	0	10,144	94,776	40,742	145,662
France								
Entries detained	26	31	21	13	13	25	19	148
Quantity (lbs.)	8,653	3,269	46,008	2,861	5,707	25,168	9,015	100,681
Italy								
Entries detained	3	6	3	11	7	11	12	53
Quantity (lbs.)	141	1,734	475	96,324	55,604	123,026	131,518	408,822
Netherlands								
Entries detained	0	0	3	5	3	6	1	18
Quantity (lbs.)	0	0	38,104	48,666	73,452	17,583	7,152	184,957
New Zealand								
Entries detained	0	0	0	0	0	0	0	0
Quantity (lbs.)	0	0	0	0	0	0	0	0
Others								
Entries detained	9	6	12	19	17	51	30	144
Quantity (lbs.)	57,964	105,030	44,945	324,037	212,959	595,028	367,871	1,707,832
Total								
Entries detained	40	44	39	54	50	105	70	402
Quantity (lbs.)	67,556	150,940	129,532	522,146	439,552	960,199	707,004	2,876,929

Source: GAO analysis of FDA data.

Table 11: Detentions of Imported Casein for Health-related Reasons by Country of Origin, Fiscal Years 1985-91

Country of origin	Fiscal year							Total
	1985	1986	1987	1988	1989	1990	1991	
Australia								
Entries detained	0	0	0	0	0	0	1	1
Quantity (lbs.)	0	0	0	0	0	0	42,108	42,108
Denmark								
Entries detained	0	0	0	0	0	0	0	0
Quantity (lbs.)	0	0	0	0	0	0	0	0
France								
Entries detained	0	0	0	0	0	0	0	0
Quantity (lbs.)	0	0	0	0	0	0	0	0
Ireland								
Entries detained	0	0	0	1	1	0	0	2
Quantity (lbs.)	0	0	0	46,632	55	0	0	46,687
Netherlands								
Entries detained	0	0	0	0	0	0	0	0
Quantity (lbs.)	0	0	0	0	0	0	0	0
New Zealand								
Entries detained	1	0	0	0	0	1	0	2
Quantity (lbs.)	59,524	0	0	0	0	33,069	0	92,593
Others								
Entries detained	2	0	0	0	0	0	0	2
Quantity (lbs.)	29,100	0	0	0	0	0	0	29,100
Total								
Entries detained	3	0	0	1	1	1	1	7
Quantity (lbs.)	88,624	0	0	46,632	55	33,069	42,108	210,488

Source: GAO analysis of FDA data.

Table 12: Detentions of Imported Casein for Nonhealth-related Reasons by Country of Origin, Fiscal Years 1985-91

Country of origin	Fiscal year							Total
	1985	1986	1987	1988	1989	1990	1991	
Australia								
Entries detained	0	0	0	0	0	0	0	0
Quantity (lbs.)	0	0	0	0	0	0	0	0
Denmark								
Entries detained	0	0	0	0	0	0	0	0
Quantity (lbs.)	0	0	0	0	0	0	0	0
France								
Entries detained	0	0	0	0	0	0	0	0
Quantity (lbs.)	0	0	0	0	0	0	0	0
Ireland								
Entries detained	0	0	0	0	0	0	0	0
Quantity (lbs.)	0	0	0	0	0	0	0	0
Netherlands								
Entries detained	0	0	0	0	0	0	0	0
Quantity (lbs.)	0	0	0	0	0	0	0	0
New Zealand								
Entries detained	0	0	0	0	0	0	0	0
Quantity (lbs.)	0	0	0	0	0	0	0	0
Others								
Entries detained	0	0	1	0	0	0	1	2
Quantity (lbs.)	0	0	4	0	0	0	112,000	112,004
Total								
Entries detained	0	0	1	0	0	0	1	2
Quantity (lbs.)	0	0	4	0	0	0	112,000	112,004

Source: GAO analysis of FDA data.

Table 13: Detentions of Imported Butter for Nonhealth-related Reasons by Country of Origin, Fiscal Years 1985-91

Country of origin	Fiscal year							Total
	1985	1986	1987	1988	1989	1990	1991	
Canada								
Entries detained	0	0	0	1	0	0	0	1
Quantity (lbs.)	0	0	0	36	0	0	0	36
Denmark								
Entries detained	0	0	0	0	0	0	0	0
Quantity (lbs.)	0	0	0	0	0	0	0	0
France								
Entries detained	0	0	0	1	0	0	1	2
Quantity (lbs.)	0	0	0	110	0	0	330	440
Ireland								
Entries detained	0	0	0	0	0	0	0	0
Quantity (lbs.)	0	0	0	0	0	0	0	0
New Zealand								
Entries detained	0	0	0	0	0	0	0	0
Quantity (lbs.)	0	0	0	0	0	0	0	0
Germany								
Entries detained	0	0	0	0	0	0	0	0
Quantity (lbs.)	0	0	0	0	0	0	0	0
Others								
Entries detained	0	0	0	0	1	9	0	10
Quantity (lbs.)	0	0	0	0	264	5,344	0	5,608
Total								
Entries detained	0	0	0	2	1	9	1	13
Quantity (lbs.)	0	0	0	146	264	5,344	330	6,084

Note: No imported butter entries were detained by FDA for health-related reasons during fiscal years 1985 to 1991.

Source: GAO analysis of FDA data.

Table 14: Detentions of Dry Milk/Frozen Cream for Nonhealth-related Reasons by Country of Origin, Fiscal Years 1985-91

Country of origin	Fiscal year							Total
	1985	1986	1987	1988	1989	1990	1991	
Australia								
Entries detained	0	0	0	0	0	0	0	0
Quantity (lbs.)	0	0	0	0	0	0	0	0
Canada								
Entries detained	0	0	0	0	0	0	0	0
Quantity (lbs.)	0	0	0	0	0	0	0	0
Netherlands								
Entries detained	0	0	0	0	0	0	0	0
Quantity (lbs.)	0	0	0	0	0	0	0	0
New Zealand								
Entries detained	0	0	0	0	0	0	0	0
Quantity (lbs.)	0	0	0	0	0	0	0	0
United Kingdom								
Entries detained	0	0	0	0	0	0	0	0
Quantity (lbs.)	0	0	0	0	0	0	0	0
Germany								
Entries detained	0	0	0	0	0	0	0	0
Quantity (lbs.)	0	0	0	0	0	0	0	0
Others								
Entries detained	2	0	0	0	0	2	0	4
Quantity (lbs.)	254	0	0	0	0	1,269	0	1,523
Total								
Entries detained	2	0	0	0	0	2	0	4
Quantity (lbs.)	254	0	0	0	0	1,269	0	1,523

Note: No entries of imported dry milk/frozen cream were detained by FDA for health-related reasons for fiscal years 1985 to 1991.

Source: GAO analysis of FDA data.

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